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Transforming Research to Practice Change: Standards for Reporting Implementation Studies (StaRI) Guidelines

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Researchers, educators, and clinicians working in the field of geriatric medicine, confront significant challenges overcoming the cognitive, political, financial, and logistical obstacles that slow either the uptake of effective interventions or the de-implementation of ineffective interventions. Long-held faith that peer-reviewed publications, clinical guidelines incorporating the highest quality research, and continuing medical education were efficient vehicles to translate evidence into clinical practice have been challenged.[1] The Institute of Medicine estimates that the path from definitive published evidence to routine bedside uptake of that knowledge requires an average of 17 years – and even then only 14% of the evidence is used.[2] For example, a review of 30 proven interventions for chronic heart failure care, assessed routine practice in the institutions that had published the original randomized controlled trials; only half of the United States centers had implemented or sustained the practice that they had demonstrated to be effective.[3]

The path from knowledge to healthcare delivery is complex with multiple barriers between medical researchers, clinicians, and patients depicted by the "Knowledge Translation Pipeline" (Figure).[4] Maintaining awareness of contemporary research is increasingly difficult with over 3500 biomedical publications appearing on PubMed daily, and critical reading and healthy skepticism is necessary because some estimate much published research is misleading.[5] Medical investigators too often work in silos separated from clinicians, which leads to research that asks the wrong questions, targeting patients dissimilar from those for whom the intervention is

intended, using resources unavailable in many settings, and/or assessing relatively less important surrogate outcomes.[6,7]

Methods to transform health services research into healthcare delivery include quality improvement projects and implementation science. Although the shared objective of quality improvement and implementation science researchers is to improve the health of individuals and populations, and/or the efficiency of healthcare systems, the paths to attaining these goals diverge with the methods. Quality improvement typically consists of local initiatives that seek to adapt the ergonomics, efficiency, and behavior within one healthcare setting perhaps using rapid implementation cycles. Such interventions may be unique to the setting in which they are employed with limited external validity. In contrast, implementation science encompasses the key components of knowledge translation including whether it reaches the intended audience, whether an intervention is delivered as intended, what personnel and resources are required to implement the intervention, and whether it can be reproduced and sustained in diverse settings.[8,9]

Healthcare providers have consistently criticized the inadequate description in reports, which provide insufficient detail to enable implementation strategies to be reproduced and support the roll-out of effective practice.[10,11] The Standards for Reporting Implementation Studies (StaRI) guidelines were developed by an international collaboration of implementation science experts to provide a transparent and uniform structure to describing the methods, results, and interpretation of implementation science research.[12,13] The StaRI group used methodology recommended by Enhancing the Quality and Transparency of Health Research (EQUATOR, see http://www.equator-network.org/) including inviting the views of clinicians, educators, journal editors, and implementation science experts at different points in the process to ensure acceptable and thorough reporting standards.[14,15] The StaRI checklist has 27-items and is freely available via http://www.equator-network.org/reporting-guidelines/stari-statement/ not only to investigators, reviewers, and editors but also to commissioners, managers and professionals seeking to improve healthcare services. StaRI is underpinned by a number of key concepts.

- A unique feature of StaRI is the two strands of reporting: (1) Implementation Strategy and (2) Intervention. The intervention is the evidence-based technology or resource that is under-provided (or in the case of de-implementation research overused in lieu of a more efficacious or cost-effective alternative); the implementation strategy focuses on the components of the model used to promote delivery of the intervention, including leadership resources, personnel, costs, and infrastructural requirements.[16]
- A robust and explicit description of the context within which the implementation strategy is deployed provides details that are too often lacking in current manuscripts. Understanding the context is essential to understanding why an implementations strategy was effective (or not). Readers need to know about features of the political, financial or health service context that may influence the adoption of the intervention, and understand the local scenario, providers, or resource constraints that influenced adaptation of the strategy.
- An explicit description of how the implementation strategy was expected to work is crucial. For example, a recent implementation study reported in the *Journal of the American Geriatrics Society* (JAGS) found no benefit from training physical therapists to deliver home-based cognitive behavioral self-management for older adults with activity-limiting pain.[17] However, the authors do not report the program logic used to adapt the therapist's delivery of cognitive behavioral therapy or the fidelity with which self-management was delivered in the

home, or the patients' adherence to the program. Readers therefore remain uncertain whether lack of effectiveness equates to an inadequate implementation strategy (educating physical therapists), a weak intervention (home-based cognitive behavioral therapy for pain), poor adherence (limited uptake by patients) or some combination of these factors.

Adherence to StaRI reporting guidelines, which will now appear in the *JAGS* author instructions for implementation science submissions, provides manuscript preparation recommendations that will enable readers to identify implementation studies, differentiate the components that work from those that do not, and decide how closely the context matches their own situation. Most, though not all, EQUATOR research indicates that adherence to appropriate reporting recommendations standardizes key methodological reporting across journals and specialties,[18,19] though some researchers and journals underemphasize and underuse applicable recommendations.[20,21]

Disseminating and using the StaRI guidelines also presents challenges. There are 358 reporting guidelines registered on the EQUATOR website covering methodologies such as randomized controlled trials (RCTs) including a number of extensions to address RCT sub-types, observational studies, diagnostic and prognostic research, meta-analyses, and quality improvement. None, however, addressed the unique philosophy of implementation research whilst encompassing a broad range of methodologies.[8] The StaRI guidelines were designed to complement rather than duplicate existing EQUATOR reporting standards. For example, a pragmatic randomized trial design of an implementation study should adhere to StaRI, but include the applicable elements of the CONSORT-Pragmatic standard.[22]

Implementation science is concerned with promoting uptake of proven interventions into routine practice, raising the question as to when evidence is sufficiently compelling to justify implementation. Who defines the "best evidence" and at what threshold does a new intervention become "high-quality"? Research is needed to develop objective, consensus-based approaches to defining "best evidence" that should feed into the pipeline of implementation science.[23,24]

StaRI challenges word counts. At the journal-level, publishers increasingly pressure editorial boards to limit word counts to reduce manuscript production costs. Implementation science is more complex than two arm RCTs and will necessitate innovative or flexible approaches to accommodate the required descriptions of implementation strategy, intervention and context required. Use of on-line repositories, or prior publication of descriptions of implementation strategies may resolve the tension between the need for brevity and adequate description – but open access to these developmental or descriptive papers will be essential if the reader is not to be frustrated by being advised that 'the description has been previously reported' in an unobtainable publication. At the author-level, academic currency is traditionally quantified and compared across investigators by raw publication numbers, citation counts, and various measures of research impact.[25] Authors will have to choose between one coherent and adequately thorough manuscript (which will require a paradigm shift in rewarding academic productivity) and multiple publications risking accusations of 'salami publishing' none of which convey the full story. More positively, the increased interest in impact has raised the profile of applied research and implementation researchers will find it relatively easy to prove the impact of their work on clinical practice.

Finally, the existence of EQUATOR reporting guidelines does not guarantee higher quality research, but the hope is that the concepts elucidated in StaRI will highlight and clarify aspects of study design as CONSORT has for RCTs.[19] Aging societies worldwide present complex problems for healthcare systems across medical and surgical specialties. Incorporating StaRI reporting guidelines should clarify understanding of the key components required to implement effective interventions or de-implement harmful or wasteful strategies using a scientific approach, and ensure that reports of the implementation studies are easily identifiable and well described to inform future practice today – rather than in 17-years' time.

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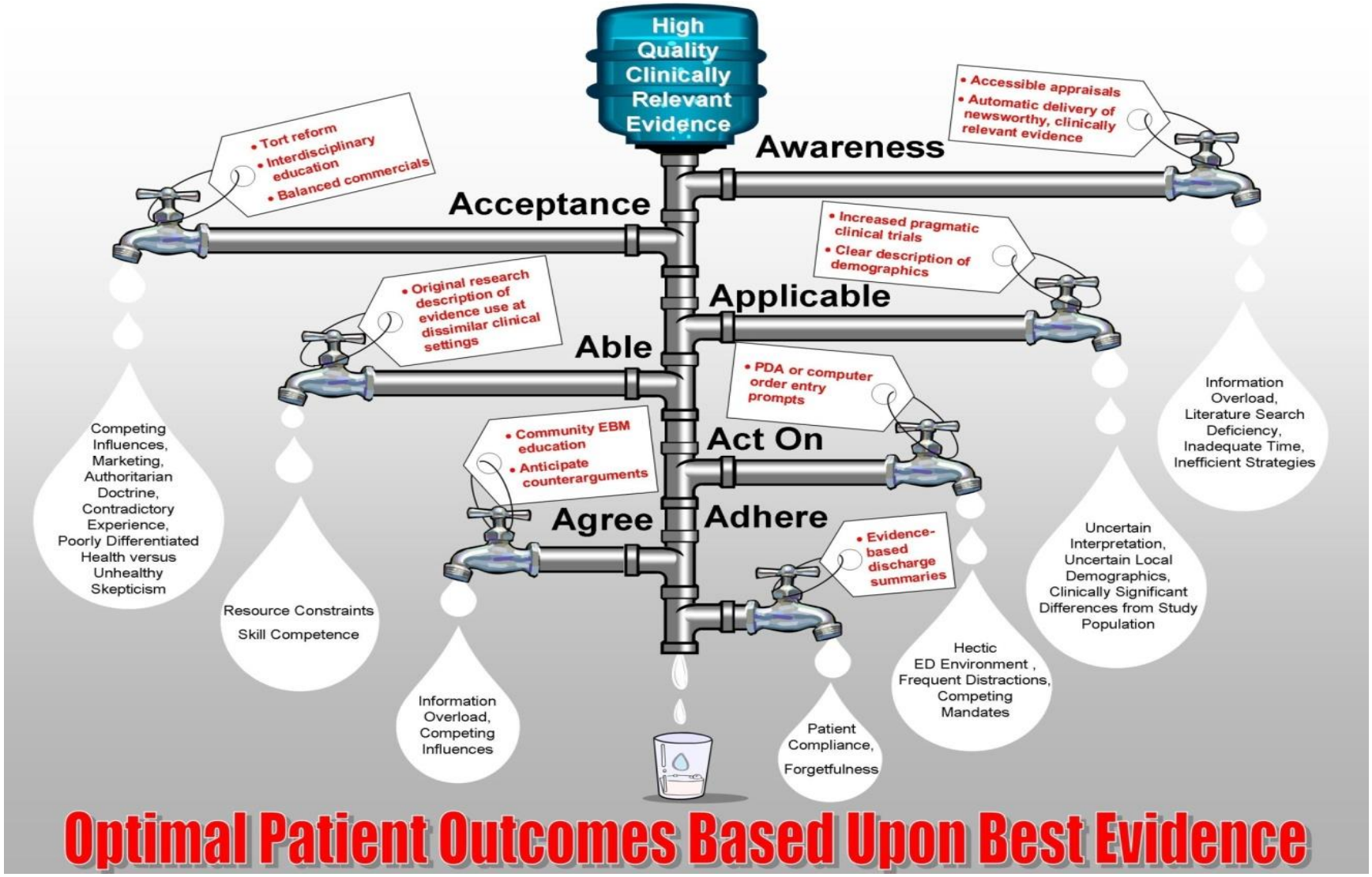
Figure 1. **The Knowledge Translation Pipeline (from Reference 3)**


High Quality Clinically Relevant Evidence
Awareness
Applicable
Act On
Adhere
Agree
Able
Acceptance
• Accessible appraisals
• Automatic delivery of newsworthy, clinically relevant evidence
• Increased pragmatic clinical trials
• Clear description of demographics
• PDA or computer order entry prompts
• Evidence-based discharge summaries
• Community EBM education
• Anticipate counterarguments
• Original research description of evidence use at dissimilar clinical settings
• Tort reform
• Interdisciplinary education
• Balanced commercials
Information Overload, Literature Search Deficiency, Inadequate Time, Inefficient Strategies
Uncertain Interpretation, Uncertain Local Demographics, Clinically Significant Differences from Study Population
Hectic ED Environment , Frequent Distractions, Competing Mandates
Patient Compliance, Forgetfulness
Information Overload, Competing Influences
Resource Constraints
Skill Competence
Competing Influences, Marketing, Authoritarian Doctrine, Contradictory Experience, Poorly Differentiated Health versus Unhealthy Skepticism
Optimal Patient Outcomes Based Upon Best Evidence